PASSIVE AND WIRELESS DISPLACEMENT MEASURING DEVICE USING PARALLEL SENSORS

RELATED PATENT APPLICATION

This application is a divisional of U.S. Patent Application No. 09/789,832, filed February 20, 2001, and entitled "*Passive and Wireless Displacement Measuring Device*," which claims the benefit of U.S. Provisional Application No. 60/200,835, filed May 1, 2000 and entitled "*Passive Spinal Fusion Diagnostic System*".

TECHNICAL FIELD OF THE INVENTION

This invention relates to devices for measuring displacement, and more particularly to a wireless device that can be implanted between two adjacent objects and used to measure changes in their separation distance.

BACKGROUND OF THE INVENTION

Displacement and proximity sensors play large roles in the automotive, aerospace, food, beverage, metal, and computer industries. The increase in automation has vastly increased the demand for such sensors. This demand is due to the replacement of outdated plant equipment and the overall increase in factory automation.

Of the sensors in the proximity and displacement sensor market, inductive (magnetic) and photoelectric sensors are probably the most popular. Other types of displacement sensors are capacitive sensors, ultrasonic sensors, potentiometric sensors, laser sensors, and ultrasonic sensors.

Magnetic displacement sensors include LVDT (linear variable differential transform) sensors, hall effect sensors, and magnetostrictive sensors. LVDT sensors use three coils, a primary coil and two secondary coils. The secondary coils are connected to establish a null position. A magnetic core inside the coil winding assembly provides a magnetic flux. When the core is displaced from the null position, an electromagnetic imbalance occurs. Hall effect sensors are based on a voltage that is generated in one direction when a current and a magnetic field pass through semiconductor material in the other two perpendicular directions.

Variations of magnetic and inductive sensors have been developed with one or two coils. A disadvantage of many magnetic and inductive designs is the need for an electrical connection to the sensor.

SUMMARY OF THE INVENTION

One aspect of the invention is a sensor/interrogator system for measuring displacement between two adjacent objects. The sensor has a magnetic rod, a sensor coil, and a capacitor attached to the sensor coil so as to form a tuned circuit. A first end of the rod is insertable into a first end of the coil and moveable along the axis of the coil. The rod has an end mount at its second end, as does the coil, which permits the sensor to be attached between the two objects. When the objects move, the rod moves along the coil. The interrogator having at least one interrogator coil, transmit circuitry for delivering to the sensor coil an excitation signal through a range of frequencies, and receive circuitry for receiving a response signal from the sensor coil. The change in frequency of the response signal is related to the amount of motion of the rod inside the coil.

For orthopedic applications, an advantage of the invention is that it provides a non-invasive system that incorporates an implantable passive sensor and an external interrogating device. The system is especially useful to diagnose spinal fusion postoperatively, by measuring the changes in separation of the vertebrae. The sensor response can be correlated to the relative motion of the vertebrae. The system can also be used for diagnosing other types of bone fusion, such as motion between an orthopedic implant and the surrounding bone. Small motions in this case, indicate implant loosening. The system can also measure motion between two bone

segments of a fracture. Small motions in this case, indicate non-fusion of the fracture.

For spinal fusion applications, when a patient postoperatively complains of pain, the physician needs to determine whether the pain is the same as the preoperative pain or if it is from a different source. The sensor/interrogator system may be used to diagnose whether the spine has fused (a new source of pain must be the cause) or not (the same area may be causing the pain). This determination will affect the patient's treatment. In addition, as the patient is monitored postoperatively, the physician can use the information from the system to guide the patient's rehabilitation program, allowing a faster recovery time and reduced healthcare costs. In the past, methods to diagnose spinal fusion have used radiographic tools. In contrast, the system described herein does not need radiography, and allows the physician to diagnose spinal fusion in his or her office.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 illustrates a sensor in accordance with the invention, affixed between two vertebra of the human spine.

FIGURE 2 illustrates a sensor similar to that shown in FIGURE 1, with its rod and coil separated.

FIGURE 3 illustrates the sensor of FIGURE 2, with its rod inserted into the coil, and with the addition of a protective sheath.

FIGURE 4 illustrates the placement of an interrogator used to transmit an excitation signal to the sensor and receive a response signal from the sensor.

FIGURE 5 illustrates one implementation of the circuitry of the interrogator of FIGURE 4.

FIGURE 6 illustrates an example of the signal receive circuitry of the interrogator of FIGURE 5.

FIGURE 7 illustrates a two-coil embodiment of the interrogator of FIGURE 4.

FIGURE 8 illustrates a three-coil embodiment of the interrogator of FIGURE 4.

FIGURE 9 illustrates the relationship of the sensor frequency response, as detected by the interrogator, and the displacement of the sensor rod relative to the sensor coil.

FIGURE 10 illustrates a sensor-pair configuration, which may be used as an alternative to the sensor of FIGURE 1.

FIGURE 11 illustrates an application of the sensor-pair of FIGURE 10.

DETAILED DESCRIPTION

Single Sensor Configuration

FIGURE 1 illustrates a displacement sensor 10 in accordance with the invention. In the example of FIGURE 1, sensor 10 is used to measure displacement along the human spine and is implanted within the lumbar spine. Sensor 10 is comprised of rod 12, coil 13, capacitor 14, and end mounts 15.

Sensor 10 is particularly useful in environments in which wires and other types of electrical leads are impractical. As explained below, to obtain a displacement measurement, an interrogator device (not shown in FIGURE 1) is placed near sensor 10. In the orthopedic application of FIGURE 1, where sensor 10 is implanted, the interrogator device is external to the body.

The orthopedic application of FIGURE 1 is but one application of sensor 10. In general, sensor 10 could be implanted between any two objects and used to noninvasively measure the displacement between them. For example, for structural applications, sensor 10 could be placed between blocks of a bridge or building. The size and robustness of sensor 10 is easily scaled to the type of application and to the environment in which it is to be used.

Regardless of the application, the objects whose displacements are to be measured are "adjacent" in the sense that an end mount 15 of sensor 10 may be attached to each object. The only limitation is that the end mounts 15 of sensor 10 each be affixed in a manner that

permits sensor 10 to "bridge" the two objects and that permits coil 13 and rod 12 to move relative to each other if the objects move. The term "objects" is used herein in the broadest sense; the two "objects" between which sensor 10 is attached could be two surfaces of two different pieces of material or two surfaces of a single piece of material.

End mounts 15 are at either end of sensor 10. Each end mount 15 is attached to one of two objects whose displacement is to be measured. In the example of FIGURE 1, end mounts 15 are ball joints. Motion is measured along a single axis - that of the sensor 10. There may be more degrees of freedom, but only axial motion is sensed. Screws are used to attach the end mounts 15 to the vertebrae through holes in end mounts 15.

FIGUREs 2 and 3 illustrate sensor 10 with its coil 13 and rod 12 segments separated and coupled, respectively. In FIGURE 2, sensor 10 is shown without end mounts. FIGURE 3 further illustrates a flexible sheath 21, which may be placed over rod 12, coil 13, and capacitor 14. Sheath 21 is typically used when sensor 10 is implanted for biomedical applications, such as the orthopedic application of FIGURE 1.

In operation, as explained below, the motion of rod 12 within coil 13 can be correlated to the relative motion of the two objects to which sensor 10 is attached. In the example of FIGURE 1, the motion of rod 12 within coil 13 can be correlated to lumbar spine motion and therefore to spinal fusion success. Sensor 10 may be positioned between any two vertebrae involved in the

spinal fusion or on the ends of a spinal fusion segment. More than one sensor 10 could be implanted. Sensor 10 can be attached to the anterior or anterolateral spine or the vertebral body. Sensor 10 can be attached to the posterior spine on either the spinous processes, transverse processes or the facets. Alternative attachment sites may be necessary given the specific anatomy of a patient. In the example of FIGURE 1, sensor 10 is attached to the spinous processes.

A vast variety of attachment mechanisms can be used as end mounts 15, such as rivets, epoxy, or spring mechanisms. End mounts 15 may themselves be some type of screw or insertion post. For some applications, the attachment means should rigidly attach sensor 10 to the objects whose displacement is to be measured, minimizing any relative motion between sensor 10 and the objects to which it is attached. For other applications, end mounts 15 might be in the form of a loop or bushing that permits slight misalignment.

Rod 12 is oriented along the direction of expected motion and travels along the longitudinal axis of coil 13 as motion occurs. Rod 12 is made from a magnetically permeable material such as ferrite. The optimum rod size can be determined experimentally and depends on the application; sensor 10 is easily scaled in size for different applications. The optimum rod size may involve a tradeoff between the size of the objects whose displacement is to be measured, their expected displacement, and the distance between sensor 10 and the external interrogator device.

For orthopedic applications, rod 12 will typically range in length from one-half inch upwards, depending on where it is attached to the spine. Its diameter will usually range from one-eighth to one-quarter inch.

Coil 13 is comprised of coiled wire, the diameter of which again depends on the application and other dimensions of sensor 10. The inner diameter of coil 13 is slightly larger than the outer diameter of rod 12. For best performance, the length of coil 13 may range from three-quarters the length of rod 12 to twice as long as rod 12.

For orthopedic applications, a typical range of wire diameters is 28 AWG (American Wire Gauge) to 40 AWG. The dimensions of coil 13 might range from one-fourth to three-quarters inch long by one-eighth to three-eighths inch in internal diameter. For other applications, the dimensions of coil 13 again depend on considerations such as the environment in which sensor 10 is placed and on the expected distance from the external interrogator device.

Capacitor 14 is attached to coil 13, and is chosen to set the resonant frequency of sensor 10. A typical frequency range for various applications is 1 to 10 MHz. For this frequency range, the size of capacitor 14 might range from 50 pF to 0.01 μF.

A suitable capacitor size for spinal fusion applications has been determined experimentally as 220 to 1000 pF. However, for other applications, the capacitor size depends on considerations such as the maximum allowable size of the coil 13, desired resonant frequency

of sensor 10, and the need to minimize the effects of stray capacitance on the resonant frequency.

Sensor 10 uses a tuned radio frequency circuit to achieve displacement measurement. The resonant frequency (f) is set by the value of an inductance (L) and the capacitance (C) of capacitor 14, and is given by:

$$f = \frac{1}{2\pi\sqrt{LC}}$$

The inductance is determined by the plunge depth of rod 12, which, in turn, is determined by the spacing between the two objects to which sensor 10 is attached.

Means other than a capacitor 14 external to coil 13 may be used to provide a resonant circuit. For example, the coil 13 could be made self resonant. Alternatively, it could be resonated with stripline, with a gyrator, or with a capacitor in the interrogator unit. Furthermore, although resonance improves the output signal, the concept of measuring relative displacement remotely using a variable magnetic coupling between two magnetically active objects may be implemented without resonance.

Sensor 10 is passive in that no battery or other energy source is required to power it. When excited by the interrogator device, its tuned circuit absorbs and re-radiates a signal at the sensor resonant frequency. The resonant frequency changes as the plunge depth of the rod 12 changes. This permits displacement of rod 12 within coil 13 to be inferred and used to measure displacement between the objects. For the application of FIGURE 1, the spacing between vertebrae is inferred from

a measurement of the resonant frequency of the tuned circuit.

For biomedical applications, such as the spinal application of FIGURE 1, sensor 10 might be desired to be biocompatible. These considerations call for the use of biocompatible materials for each component, coating the components with a biocompatible material, or covering sensor 10 with a biocompatible cover to achieve biocompatibility. One of these methods, as well as any combination of these methods, can be used. The method chosen should not interfere with the ability of rod 12 to move within coil 13.

Another consideration for biomedical and other applications that call for sensor 10 to be placed in a fluid environment, is the need to prevent shorting between the elements of sensor 10. A sheath, such as sheath 21 of FIGURE 3, may be desirable to prevent shorting and permit proper functioning. Sheath 21 may be fabricated as a rubber or plastic sleeve, latex tubing, or heat shrink coating. Biocompatible materials similar to those used for angioplasty could be used.

A feature of sensor 10 is that it does not interfere with normal motion of the objects to which it is attached. Specifically, for orthopedic applications, sensor 10 does not compromise the normal kinematics of the body. Sensor 10 may be attached to anatomic positions such as the spinous process or facet that will not interfere with spine motion. In addition, sensor 10 can be used with implanted fixation devices such as

pedicle screw fixation systems or spinal fusion cages and can be viewed radiographically.

Interrogator

FIGURE 4 illustrates interrogator 40, placed against a patient's back during displacement measurement. Thus, for orthopedic or other biomedical applications, sensor 10 may be internal to the body, whereas interrogator 40 is external and introduced only when measurements are desired. Thus, in general, sensor 10 is not disruptive to normal movement or operation of the environment in which it is used; interrogator 40 need only be in place when measurements are to be obtained.

During a measurement session, interrogator 40 is placed proximate to sensor 10. To obtain a displacement measurement, interrogator 40 "reads" sensor 10 using an interrogation coil or set of coils and appropriate circuitry.

The distance between interrogator 40 and sensor 10 need not remain constant in order for the system to work correctly. An increase in separation distance will result in a reduced signal, but will not affect the frequency response.

FIGURE 5 is a block diagram of one example of interrogator 40. It has an interrogation coil 51, a mutual inductance bridge 52, signal transmit and receive circuitry 53, a swept frequency source 56, and a driver 57.

During a measurement session, interrogation coil 51 is placed sufficiently near sensor 10 so as to loosely couple the sensor coil 13 and interrogation coil 51. The

interrogation coil 51 is driven by the swept frequency source 56 through the mutual inductance bridge 52 over a frequency span that encompasses the range of possible resonant frequencies of sensor 10. This frequency range is bounded by the frequency associated with minimum displacement and the frequency associated with maximum displacement of rod 12 relative to coil 13. As the frequency sweeps through the resonant frequency of sensor 10, sensor 10 absorbs and re-radiates energy, resulting in a change in the output of the mutual inductance bridge 52.

FIGURE 6 illustrates an example of signal transmit and receive circuitry 53. It has a signal detector circuit 61, an analog to digital converter 62, a microcontroller 63, memory 65, and a data output interface 64. Its functions include control of the swept frequency source 56, calibration of the mutual inductance bridge 52, extraction of the measured data, and formatting of the user output display.

In the example of FIGUREs 5 and 6, frequency source 56 is a commercially available integrated circuit, but other types of frequency generation techniques may be implemented. At the receive side of interrogator 40, the output of frequency source 56 may be mixed with the received signal for coherent detection. The amplitude of the resulting signal will then vary with frequency. This mixing technique is useful to enhance the signal to noise ratio and sensitivity of the interrogator.

In the example of FIGURE 5, coil 51 is a single coil loop antenna that transmits an excitation signal to coil

13 and receives a response signal. In other embodiments, multiple coils (transmit and receive) could be used. Various AC coupling or mechanical nulling techniques can be used to minimize the offset portion of the signal. This permits increased gain of the received signal, and thereby increases the sensitivity of interrogator 40.

FIG. 7 illustrates another example of interrogator 40. Two coils 71 and 72 are arranged in a null coupling geometry. The coils 71 and 72 are overlapped side by side at the critical coupling spacing so that the field from the transmit coil 71 nulls that of the receive coil 72. A differential amplifier 73 receives and amplifies the output of the receive coil 72.

FIGURE 8 illustrates a three coil geometry of the interrogator 40. Coil 81 is a transmit coil. Two receive coils 82 are connected as a differential receiver and cancel the transmitted signal. A differential amplifier 83 measures the difference between the positive signal from one receive coil 82 and the equal in amplitude but opposite in phase signal from the other receive coil 82, and provides an amplified output of the difference.

For the interrogator embodiments of FIGUREs 7 and 8, interrogation is accomplished by loosely coupling to sensor 10 and sweeping the frequency over the anticipated resonant frequency of the sensor. The transmit coil 71 or 81 and receive coil(s) 72 or 82 can both couple to sensor coil 13, but not to each other. As the frequency sweeps through the resonance of sensor 10, energy is coupled from the transmit coil 71 or 81 to the receive coils(s)

72 or 82 via the sensor's tuned circuit. The output of the receive coil(s) 72 or 82 is detected and processed as before.

FIGURE 9 illustrates the relationship between the frequency response of sensor 10, as detected by interrogator 40, and the relative displacement of rod 12 relative to coil 13. This graph shows that displacements of approximately 0.1 mm can be resolved.

Sensor Pair Configuration

FIGURE 10 illustrates an alternative sensor configuration, comprised of a pair of sensors 100. Each sensor 100 has a rod 102, a coil 103, and a capacitor 104. Like sensor 10, the rod 102, coil 103, and capacitor 104 form a tuned circuit. However, unlike the rods of sensors 10, the rod 102 of a sensor 100 does not move relative to its coil 13. It is the displacement between sensors 100 that is of interest.

Sensors 100 are used to measure the displacement between any two locations. One sensor 100 is attached or embedded at one location, and the other sensor 100 to a nearby location.

One advantage of the configuration of FIGURE 10 is that the sensors 100 can be mounted independently, with no physical connection between the two. However, the sensors 100 should be initially placed sufficiently close together and in the correct orientation so as to form the overcoupled system described below. In general, the sensors 100 are placed substantially parallel to each other and offset axially.

Like sensor 10, sensors 100 may each have end mounts (not shown). Furthermore, an end mount might be at only one end rather than at both ends. However, an advantage of the configuration of FIGURE 10 is that sensors 100 may be simply embedded within an object or within each of two different objects; there is no need for mechanical coupling of sensors 100.

For the sensor embodiment of FIGURE 10, two tuned circuits are used, both to the same resonant frequency. Sensors 100 have a fixed frequency response. When placed in proximity to one another, the tuned circuits of sensors 100 interact and form an overcoupled resonant system. Rather than a single resonant peak, there is a double peak. The frequency separation between the peaks is sensitive to the spacing between the two sensors 100. Relative motion between the sensors 100 is detectable by a shift in peak separation.

FIGURE 11 illustrates the application of sensors 100 for measuring spinal fusion. Rods 102 are threaded on the end to allow them to be screwed directly into the spine. If a large area of the spine is of interest, numerous sensors 100 could be implanted. The relative motion of sensors 100 can be correlated to spine motion and therefore spinal fusion success.

The sensor-pair configuration of FIGUREs 10 and 11 can be interrogated with an interrogator that is similar to interrogator 40. The primary difference is that the data is inferred from the frequency separation of a double peak response instead of the location of a single resonant peak.

Orthopedic Applications

In practice, for orthopedic applications, one or more sensors 10 are implanted during surgery. The length of rod 12 is chosen so that at rest, rod 12 is positioned within coil 13 only one-quarter to three-quarters the length of rod 12. For the sensor-pair configuration of FIGURE 10, the two sensors 100 are placed parallel to each other and offset axially.

When the patient visits the physician, the interrogator 40 is secured to the patient. It is placed sufficiently close to the patient such that the distance between the sensor 10 (or sensors 100) and the interrogator 40 is minimized. As the patient moves, the internal sensor 101 frequency response changes will be measured and correlated to motion.

For the spinal fusion application of FIGURE 1, theoretically, if the spinal fusion surgery was successful, there should be no measurable motion between the spinal fusion segments. The changes in the sensor response can then be correlated to relative motion of the vertebrae and to spinal fusion success. Unlike flexion-extension x-rays and CT scans which measure a static position and compare it to another static position, sensor 10 and interrogator 60 can dynamically measure motion and any sensor response changes can be correlated to fusion success. Dynamic measurement and analysis of motions are completed through automated data analysis, allowing the physician to see the outcome of the diagnostic test immediately after the test is completed.

Therefore, the spinal fusion healing progression could also be objectively observed over time.

The same system can be used for diagnosing other types of bone fusion. For instance, the system can measure motion between an orthopedic implant and the surrounding bone. Small motions in this case would indicate implant loosening. The system can also measure motion between two bone segments of a fracture. Small motions in this case would indicate a non-fusion of the fracture. Therefore, the invention provides a very simple and consistent measuring system for diagnosing small motions between bones or between orthopedic implants and bone surfaces without being invasive. In general, the sensors are attached to "skeletal objects" whether they be natural or artificial.

Other Embodiments

Although the present invention has been described in detail, it should be understood that various changes, substitutions, and alterations can be made hereto without departing from the spirit and scope of the invention as defined by the appended claims.